K 120690

510(k) Summary

JUN 2 2 2012

As Required by 21 CFR 807.92

1. **Date of Preparation:** Feb, 24, 2012

2. **Sponsor Information:**
   Tiger Medical Products Ltd.
   Liulin Tower, Suit 1910, 1 Huaihai Zhong Road
   Shanghai 200021, China

   Contact Person:
   David Wang, RA Manager
   Tiger Medical Products Ltd.
   Phone Number: 86-21-6386 6300
   Fax Number: 86-21-6386 5086
   E-mail: davidwang@tigermedicalgroup.com

3. **Submission Correspondent**
   David Wang, RA Manager, Tiger Medical Products Ltd.
   Phone Number: 86-21-6386 6300
   Fax Number: 86-21-6386 5086
   E-mail: davidwang@tigermedicalgroup.com

4. **Device Name and Classification:**
   a. Common Name: insulin pen needle
   b. Regulation Number: 880.5570
   c. Product code: FMI
   d. Class: II
   e. Review Panel: General Hospital

5. **Predicate Device Identification:**
   K051899
   Trade Name: BD Pen Needles

   K112332
   Trade Name: Fine Ject Insulin Pen Needle

6. **Device Description:**

Insulin pen needle is a single-use device, which consists of needle tube, needle shield, needle seat, needle seat protection cover, and seat seal paper. Needle gauge includes 29G, 30G, 31G, and 32G. Needle length can be produced to various sizes.
After sterilization by EO, it's sterile, pyrogen free, and non-toxic. Its shelf life is 5-year.

7. Summary of Non-clinical Testing Data

Bench test proves the subject device complies with requirements of ISO 11608-2, ISO 9626, and ISO 7864. Besides, biocompatibility tests prove it meets applicable requirements of ISO 10993.

8. Statement of Intended Use:

Insulin pen needle is intended for use with pen injector device for subcutaneous injection of insulin.

9. Summary of Comparison with Predicate Devices

Item	Insulin pen needle	BD pen needles (K051899)	Fine Ject Insulin Pen Needle (K112332)
Intended use	Insulin pen needle is intended for use with pen injector device for subcutaneous injection of insulin.	BD pen needle is intended for use with pen injector device for subcutaneous injection of drugs, including insulin and exenatide.	Fine Ject insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.
Needle gauge and length	Various sizes	Various sizes	Various sizes
Labeling and labels	Meet FDA requirements	Meet FDA requirements	Meet FDA requirements
Needle tube material	SUS 304 stainless steel	Stainless steel	Stainless steel
Material of needle seat, needle shield, and needle seat protection cover	PP	Unknown plastic	Unknown plastic
Material of needle seat seal	Dialysis paper	Paper	Paper
Performance specification (technology characteristics)	Conforms to ISO 11608-2	Conforms to ISO 11608-2	Conforms to ISO 11608-2
Biocompatibility	Conforms to ISO 10993	Conforms to ISO 10993	Conforms to ISO 10993
Sterility	SAL: $1x10^{-6}$ EtO Sterilization	SAL: $1x10^{-6}$ Gamma irradiation	SAL: $1x10^{-6}$ Gamma irradiation

10. Substantial Equivalence Conclusion

The subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2012

Mr. David Wang
Regulatory Affairs Manager
Tiger Medical Products, Limited
1 Huaihai Zhong Road
Liulin Tower, Suite 1910
Shanghai, China 200021

Re: K120690
Trade/Device Name: Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 17, 2012
Received: May 17, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120690

Device Name: Insulin Pen Needle

Indications for Use:

Insulin pen needle is intended for use with pen injector for subcutaneous injection of insulin.

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120690